PTO/PCT Rec'd 21 MAR 2002

FORM PTO-1390 (REV. 12-2001) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: VAS-5511A

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 10/088937

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US00/26239	25 Sept. 2000	23 Sept. 1999

TITLE OF INVENTION: Pre-Shaped Intraluminal Graft

APPLICANT(S) FOR DO/EO/US: White, Geoffrey H.; Dehdashtian, Mark; Jiminez, Theodoro; Yu, Weiyun

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [ ] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. [ ] The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is attached hereto (required only if not communicated by the International Bureau).
   b. [X] has been communicated by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. [ ] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).
7. [X] Amendments to the claims of the International Aplication under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [X] are attached hereto (required only if not communicated by the International Bureau) (Courtesy Copy)
   b. [X] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment.
14. [ ] A SECOND or SUBSEQUENT preliminary amendment.
15. [ ] A substitute specification.
16. [ ] A change of power of attorney and/or address letter.
17. [ ] A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. [ ] A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. [X] Other items or information:

Certificate of Mailing

JC13 Rec'd PCT/PTO 21 MAR 2002

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/089927	INTERNATIONAL APPLICATION NO. PCT/US00/26239	ATTORNEY'S DOCKET NUMBER VAS-5511A

21. [X] The following fees are submitted:	CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO $1040.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO $890.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO $740.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) $710.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) $100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 890	
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [X] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 130	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	14 - 20 =	-0-	x $18.00	$ -0-	
Independent claims	2 - 3 =	-0-	x $84.00	$ -0-	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $280.00	$	
TOTAL OF ABOVE CALCULATIONS =				$ 1,020	
[ ] Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.			+	$	
SUBTOTAL =				$ 1,020	
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$	
TOTAL NATIONAL FEE =				$ 1,020	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$	
TOTAL FEES ENCLOSED =				$ 1,020	
				Amount to be refunded:	$
				charged:	$

a. [ ] A check in the amount of $ _____ to cover the above fees is enclosed.

b. [X] Please charge my Deposit Account No. 501225 in the amount of $ 1,020 to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 501225. A duplicate copy of this sheet is enclosed.

d. [ ] Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Peter J. Gluck, Reg. No. 38,022
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
(949) 250-6801

Peter Gluck
SIGNATURE

Peter J. Gluck
NAME

38,022
REGISTRATION NUMBER

PRE-SHAPED INTRALUMINAL GRAFT

This application claims all Paris Convention Priority rights from Australian Provisional Patent Application No. PQ3029, filed 23 September 1999.

Field of the Invention

The present invention relates to an intraluminal device for use in the treatment of aneurysmal or stenotic disease. Particularly, the present invention relates to endovascular emplacement of structures designed to enhance a patient's vasculature, for example through the extension of ostensively aneurysmal growths, dissections or related issues.

Background of the Invention

Endovascular grafts and stented grafts are generally known to be useful in several distinct configurations. For example, it is known to use intraluminal grafts and stents of various designs for the treatment of aneurysms such as aortic aneurysms, and occlusive diseases affecting the vasculature or other vessels comprising, inter alia, the hepato-biliary and genito-urinary tracts (which are all hereinafter "vessels"). It is known to form such an intraluminal device of a sleeve in which is disposed a plurality of wire stents (see Balko A. et al (1986) *Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysms,* 40 Journal of Surgical Research 305-309; Mirich D. et al. (1989) *Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study* 170(3) Radiology 1033-1037).

In the past, such devices have commonly been used in the treatment of, or to exclude aneurysms, *see* United States Letters Patent No's. 5,782,904; 5,968,068; 6,013,092; 6,024,729; 6,045,557; 6,071,307; 6,099,558; 6,106,540 and 6,110,191 each of which is licensed or assigned to and may be available from

Edwards Lifesciences LLC (Orange County, California), the instant assignee, and each of which is expressly incorporated herein by reference.

Whatever the purpose for which an intraluminal device is being used, it has the capacity to be inserted percutaneously through a distal (or proximal) and connecting vessel to that in which the device is to be used, for example, through the femoral artery in a catheter, where the device is intended to be used in the treatment of a lesion within the aorta. Upon release of the device from the catheter it may expand to a desirable size, and may extend above and below the lesion thereby bridging the lesion. This method of inserting the device into the body of a patient is applicable where the invention is used in the treatment of aneurysmal disease or stenotic disease.

There are several potential problems associated with most known intraluminal devices. For instance, conventional grafts are not designed to follow the natural curvature of some vessels and may, therefore, kink if required to bridge a section of vessel that has a natural curvature.

Likewise, pursuant to use in particularly tortuous - or specifically diseased vessels – it is often necessary to have "taylor-made" or individually altered/modified grafts on the basis of whether an aortobi-iliac or aorto Uni-iliac emplacement is indicated.

Further to such natural curvature of a vessel, there may also be pathological curvature associated with aneurysmal disease. For example it is known that as an aneurysm situated in, for example, the aorto-iliac region expands, it can cause the artery to deviate in a direction towards the extending aneurysmal sac. This in turn may cause the vessel to shorten in length across this section of artery which may sometimes result in displacement or kinking of any intraluminal device positioned in the artery. Known devices ostensively ignore these types of individuated needs, and have heretofore neither addressed nor ameliorated the majority of the most pressing concerns and issues.

The present invention is directed to an alternative form of intraluminal device which is designed to overcome the above problems, inter alia.

Summary of the Invention

In a first aspect, the present invention consists in an intraluminal device comprising a tubular body having a length, a first end and at least one second end, wherein the tubular body has a pre-determined non-linear shape, the pre-determined shape corresponding with the shape of a non-linear shaped portion of a vessel in which the device is to be disposed.

In one embodiment the tubular body is curved along its length between the first and the at least one second end.

In a further embodiment, the tubular body forms an S-shape along its length between the first and at least one second end.

In another embodiment, the intraluminal device is a graft for bridging an aneurysm in an artery of a patient.

In a still further embodiment of the invention, when the intraluminal device is in situ within a vessel of a patient, the tubular body is configured such that it is curved along its length in an anterior-posterior plane.

In yet a further embodiment, when the intraluminal device is in situ within a vessel of a patient, the tubular body is configured such that it is curved along its length in a lateral plane.

In another embodiment, when the intraluminal device is in situ within the vessel of a patient, the tubular body is configured such that it is curved along its length in both an anterior-posterior and a lateral plane.

In a preferred embodiment, the length of the tubular graft body is made from a single piece of material that has been cut as such an angle so as to facilitate the curvature of the tubular graft body.

In a further embodiment, the first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the reminder of the first end.

In a still further embodiment of the invention, the shape of the vessel or vessel portion in which the device is to be disposed may be pre-determined and the device chosen or specifically manufactured such that the shape of the device corresponds with the shape of the vessel or vessel portion. The shape of the vessel or vessel portion may, in preferred embodiment, be determined by either ultrasound, plain abdominal films or by CT scanning. In this manner, the device is custom made from imaging of the vessel or vessel portion such that it fits securely within the vessel or vessel portion.

In a second aspect, the present invention consists in an intraluminal device comprising a tubular graft body having a length, a first end and at least one second end wherein the first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the remainder of the first end.

This has the advantage that when the device is disposed in a curved vessel, the first end of the tubular body continues to abut against the wall of the vessel in which the device is disposed even when the vessel deviates from its normal path due to pathological changes in the vessel or if the vessel has a natural curvature. Because the angled first end of the tubular body continues to abut against the surrounding wall of a vessel around substantially its entire periphery it forms a tight seal thereby reducing the likelihood of displacement of the device due to pathological deviation of a vessel from its normal path or due to the natural curvature of a vessel.

In a third aspect, the invention relates to the method for positioning an intraluminal device according to the first or second aspects of the invention, including the steps of introducing a catheter or other delivery device into a vein, artery or other vessel in the body of a patient when the device body is in a radially compressed state; causing the intraluminal device to be moved through the catheter or other delivery device until the intraluminal device extends into the vessel from a proximal end of the catheter or other delivery device; causing or allowing the itraluminal device to expand; and withdrawing the catheter or other

delivery device along with any other apparatus used to introduce the intraluminal device into the vessel.

In one embodiment, the device is adapted such that it can be brought to a substantially straight configuration along its length and radially compressed to fit internal the catheter or other delivery device. The device is moved through the catheter or other delivery device until it extends from the proximal end of the catheter or other delivery device whereupon the device expands and takes on its pre-determined curved configuration.

In a further embodiment, the catheter may be configured such that it is slightly curved along its length. The catheter may be configured such that it is curved along its length in either an anterior-posterior plane or a lateral plan or in both planes.

The intraluminal device according to this invention may be used in the treatment of aneurysms or stenotic disease. In addition to treating aortic aneurysms the device is particularly suitable for treating aneurysms of the femoral artery, the popliteal artery, the thoracic segment of the aorta, visceral arteries such as the renal and mesenteric arteries, the iliac artery and the sub-clavian artery. Further, in addition to the treatment of stenotic lesions in the peripheral vasculature, the invention may be used in the treatment of, inter alia, vessels comprising the coronary circulation. However the application of the invention for use in the treatment of stenotic disease is not to be understood as limited to the vascular system only, the device may be used to treat stenotic lesions in other vessels including, for example, those comprising the hepato-biliary and genito-urinary tracts.

In cases where the invention is to be used for the treatment of aneurysmal disease, the tubular device body is preferably formed of a thin biocompatible material such as Dacron™ or polytetrafluoroethylene (PTFE). The tube material is preferably crimped along its length to increase the flexibility of the device, however, uncrimped material may be used in suitable circumstances. In preferred embodiments of the invention for use in the treatment of aneurysmal disease, the

device body may be formed from a material having a limited amount of diametric elasticity to ensure that it can be expanded into contact with the vessel wall, forming a seal between the wall of the device and the wall of the vessel such that the escape of the vessel contents into the aneurysmal sac is prevented.

In addition, in a further preferred embodiment, the device of all three aspects of the invention includes a stent or a series of spaced apart stents which forms a framework to which may be attached an endoluminal graft. The framework of the device body may be circumferentially reinforced along its length by a plurality of separate, spaced-apart, malleable wires. Each of such wires can have a generally closed sinusoidal or zig-zag shape. The wires are preferably formed of stainless steel or another metal or a plastic which is malleable and is biocompatible. If the device is adapted such that it is substantially straight along its length to facilitate packaging within a catheter, the wires may be made from Nitinol™ or other such shape memory or heat sensitive material such that when the device is in situ within a vessel, the temperature in the vessel causes the material to take on a pre-determined configuration. The pre-determined configuration of the material in this embodiment causes the device to adopt a pre-determined curved configuration.

Each wire is preferably woven into the fabric of the device body to integrate the body and the reinforcing wires. This prevents any possibility of the wire reinforcement separating from the device body during introduction of the device or throughout its life. If the device body is of a woven material the wires may be interwoven with the device body after its manufacturer. If the device body is not woven but is knitted or of an impervious sheet material then the wires may be threaded through suitable holes formed in the device body. Alternatively the stent or stents may be continuous and may be on the radially inner or the radially outer side of the graft wall. In either case expansion of the graft or grafts will cause the graft to expand and press against the wall of the vessel into which the device has been placed. In one particular embodiment of the second aspect of

the invention, the wires are adapted such that substantially the entire periphery of the angled one end of the tubular body is reinforced.

The tubular graft body may be of the self-expandable type wherein the wires are made from a shape memory or heat sensitive material. In this embodiment, the tubular graft body is ejected from the proximal end of the catheter and into the target vessel. Once in the vessel, the tubular graft body takes on its pre-determined shape. Alternatively, the tubular graft body may be compressed within the lumen of a catheter such that upon release of the tubular graft body from the proximal end of a catheter and into the target vessel, the tubular graft body springs into its pre-determined shape. In a further embodiment, the expansion of the tubular graft body within the target vessel may be aided by way of a balloon which, when inflated pushes the tubular graft body towards the wall of the target vessel.

In addition to or instead of being circumferentially reinforced, the tubular graft body may be longitudinally reinforced. In one embodiment, a longitudinally reinforcing wired may be connected to one or more circumferentially reinforcing wires. The advantage of longitudinal reinforcement is that the tubular graft body is less likely to compress along its length during placement of the tubular graft body in the target vessel, resulting in a concertina affect.

In a still further embodiment the device of the invention is typically substantially of constant diameter along its length, that is, it is substantially cylindrical or may in some instances be frusto-conical in shape with a diameter that increases or decreases along the length of the device.

In another embodiment, the device of the invention is adapted to bridge an aneurysm that extends up to or slightly beyond an arterial bifurcation. In such a case the device is a graft which has a bifurcation at its downstream end, a so-called "trouser graft", and may be placed wholly within the primary artery. A supplemental graft may then be introduced through subsidiary arteries and overlapped with the lumen of the bifurcated part of the primary graft. In the case

of an aneurysm in the aorta, for instance, that extended into each of the common iliac arteries the primary graft would be placed in the aorta. Supplemental grafts which dock with the bifurcated end of the primary graft would then be inserted through each of the common iliac arteries.

5

Brief Description of the Drawings

One preferred embodiment of the invention is now described with reference to the accompanying drawings in which:

10 Figure 1 is a diagrammatic partially cut-away ventral view of a patient with an aortic aneurysm which has been bridged by a device according to the present invention.

Figure 2 is a simplified view of a device according to the prior art.

Figure 3 is a simplified view of a device according to the present

15 invention.

Figure 4 is a detailed longitudinal view of an aortic aneurysm that is bridged by a device according to the prior art.

Figure 5 is a detailed longitudinal view of an aortic aneurysm that is bridged by the device of the present invention.

20 Figure 6 is a side elevational view of an aortic aneurysm that is bridged by a device according to the prior art.

Figure 7 is a side elevation view of an aortic aneurysm that is bridged by the device of the present invention.

Figures 8a and 8b are representations of a delivery mechanism of one

25 embodiment of the invention.

Figure 9 likewise illustrates an alternate embodiment of a graft to be emplaced and implanted according to the teaching of the present invention.

Referring now to Figure 9, an alternate preferred embodiment shows a self-expanding or balloon expandable graft utilizing, for example, a Dacron graft.

30 According to the instant teachings a graft may be secured to a desired portion of

the aorta and iliac arteries by use of the self expanding radial force of wireforms attached to the dacron graft.

According to this teaching, a graft having at least 28mm of trunk includes a tapered portion. Balloon attachment or self-expansion may be used according to this alternate embodiment, as discussed above and claimed below.

Best Mode of Carrying Out The Invention

The present inventors have come up with novel ways to enhance the human vasculature by means of grafts which have an alternate, and substantially "pre-formed" shape for certain applications. Unlike known systems, particularly difficult anatomical structures may be ameliorated according to the instant teachings.

An endovascular graft according to the present invention is generally shown as 10 in the drawings. The endovascular graft 10 is adapted for insertion transfemorally into a patient to achieve bridging and occlusion of an aneurysm 11 present in an aorta 12. It is to be understood that the present invention has a wider applicability and could be utilized in vessels other than the aorta. As is shown in Figure 1 the aorta 12 bifurcates to form the common iliac arteries 13 which subsequently divide into the external 14 and internal 15 iliac arteries, the external iliac artery 14 eventually becoming the femoral artery 16. The aortic aneurysm is located between the renal arteries 17 and 18 and the junctions of the bifurcation of the aorta 12 into the common iliac arteries 13. The graft 10 is inserted inside a catheter 9 and introduced into one of the femoral arteries 16 of a patient. Once the catheter 9 is located appropriately with its proximal end in the aorta 12 the graft 10 is ejected from the catheter and expanded so that each end 19 and 21 is in intimated contact around its full periphery with the aorta 12. The graft 10 then bridges the aneurysm 11 and isolates any thrombosis or gelatinous

material associated with the aneurysm outside the graft 10 to reduce the risk of embolisation.

The endovascular graft 10 comprises a tube 22 of woven Dacron™. The tube is reinforced along its length with a plurality of separate spaced apart wires that are interwoven in the Dacron™. Between the two ends 19 and 21 the body of the tube 22 curves in a manner that enables the graft 10 to follow the natural or pathological contours of the aorta.

Figures 2 and 3 indicate the difference between the graft of the present invention 10 and conventionally used grafts 23. The conventionally used grafts 23 are substantially straight in design and do not account for either natural curvature of an artery or pathological curvature due to the ballooning and pulling effect of an aneurysm 11. Accordingly, when an aneurysm 11 starts to expand and the aorta 12 is pulled and forced to curve away from its normal path, the grafts of the prior art 23 can become dislodged at end 24 (see Figure 4) or kink at a point 25 along their length, (as depicted in Figure 6).

The benefit of the present invention can be seen in the graft 10 is pre-curved to align with the aorta 12 which is pulled from its natural path due to the ballooning of an aneurysm 11. Further more, end 19 of the graft 10 is angled such that it still abuts against the walls of the aorta 12 when the aorta 12 is curved out by the pull of the aneurysm. In conventional grafts 23, as the aorta 12 is curved, the end 24 of the graft may not fit against the walls of the aorta 12 and the graft can have a tendency to dislodge as a result. This can be seen in Figures 4 and 5 where the section of aorta 12 proximal the renal arteries 17 and 18 deviates towards the expanding aneurysm such that an angle is formed. The angle may in some cases be up to 90° and thus the straight shaped conventional grafts 23 sometimes do not fit securely within the aorta 12, becoming dislodged.

Whilst the graft 10 is adapted to take on a pre-determined configuration such that it aligns with a non-linear vessel, the graft 10 may be inserted into a target vessel in a substantially straight configuration. Figure 8a and 8b depict one means of introducing a graft 10 into a vessel by way of a catheter 9. The graft 10

is forced into a substantially straight configuration within the catheter 9. The graft 10 is forced into a substantially straight configuration within the catheter 9. When positioned correctly within a target vessel, the graft 10 may be ejected from the catheter 9 by way of, for example, a push rod 30 whereupon the graft 10 takes on its pre-determined curved configuration (shown in Figure 8b).

In use, the shape of the vessel in to which the device is to be disposed may be imaged and the device chosen or specifically manufactured such that the shape of the graft 10 corresponds with the shape of the vessel. Imaging may be by way of ultrasound, plain abdominal films or by CT scanning. In this manner, the graft 10 is custom made such that it fits securely within the vessel.

It will be appreciated by persons skilled in the art that numerous variations, and /or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

What is claimed is:

1. In an intraluminal device comprising at least a tubular body having a length a first end and at least one second end, the improvement which comprises:

the tubular body being of a pre-determined non-linear shape.

2. The device as defined in claim 1, wherein said pre-determined shape corresponds with a shape of a non-linear shaped portion of a vessel to house the device.

3. The device as defined in claim 2, wherein the tubular body is curved along the length between the first and the at least one second end.

4. The device as defined in claim 3, where the tubular body further comprises a sigmoid curve disposed along its length between the first and the at least one second end.

5. The device as defined in claim 4, said at least a tubular body further comprising two pieces.

6. The device as defined in claim 4, said at least a tubular body further comprising three pieces.

7. The device as defined in claim 4, said at least a tubular body further comprising four pieces.

8. The device as defined in claim 3, further comprising a graft for bridging an aneurysm in an artery of a patient.

9. The device as defined in claim 3, further comprising a graft for bridging an aneurysm in an artery of a patient.

10. The device as defined in claim 3, further comprising a curvature along the length in an anterior-posterior plane.

11. The device as defined in claim 3, further comprising a curvature along the length in a lateral plane.

12. The device as defined in claim 3, further comprising a curvature along the length in both an anterior-posterior plane and a lateral plane.

13. The device as defined in claim 3, further comprising a unitary graft assembly angled by cutting to facilitate curvature of the tubular graft body.

14. The device as defined in claim 4, further comprising a unitary graft assembly angled by cutting to facilitate curvature of the tubular graft body.

15. The device as defined in claim 3, wherein a first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the reminder of the first end.

16. The device as defined in claim 4, wherein a first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the reminder of the first end.

17. The device as defined in claim 3, wherein the shape of the vessel or vessel portion in which the device is to be disposed is pre-determined and the device specifically manufactured such that the shape of the device corresponds with the shape of the vessel or vessel portion; and,
whereby the shape of the vessel is determined by at least one of ultrasound, plain abdominal films and CT scanning.

18. The device as defined in claim 4, wherein wherein the shape of the vessel or vessel portion in which the device is to be disposed is pre-determined and the device specifically manufactured such that the shape of the device corresponds with the shape of the vessel or vessel portion; and,
whereby the shape of the vessel is determined by at least one of ultrasound, plain abdominal films and CT scanning.

19. An intraluminal device comprising a tubular graft body having a length, a first end and at least one second end wherein the first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the remainder of the first end.

20. A method for emplacing an intraluminal device according, comprising the steps of :
introducing a catheter into an artery of a patient when the device body is in a radially compressed state;
causing the intraluminal device to be moved through the catheter until the intraluminal device extends into the vessel from a proximal end of the catheter or other delivery device;
allowing the intraluminal device to expand; and,
withdrawing the catheter or other delivery device along with any other apparatus used to introduce the intraluminal device into the vessel.

(12) INTERNATIONAL APPL[redacted]ION PUBLISHED UNDER THE PATENT CO[redacted]ATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 May 2001 (03.05.2001)

PCT

(10) International Publication Number
WO 01/30270 A2

(51) International Patent Classification[7]: A61F 2/06

(21) International Application Number: PCT/US00/26239

(22) International Filing Date:
25 September 2000 (25.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PQ 3029 23 September 1999 (23.09.1999) AU

(71) Applicants: **EDWARDS LIFESCIENCES CORPORATION** [US/US]; One Edwards Way, Irvine, CA 92625 (US). **ENDOGAD RESEARCH PTY LIMITED** [AU/AU]; P.O. Box M88, Camperdown, NSW 2050 (AU).

(72) Inventors: **DEHDASHTIAN, Mark**; 1696 Palau Place, Costa Mesa, CA 92626 (US). **JIMINEZ, Theodoro**; 1402 East Alton, Irvine, CA 92614 (US). **WHITE, Geoffrey, H.**; 22 Nicholson Street, East Balmain, NSW 2041 (AU). **YU, Weiyun**; Apartment 59, Birchgrove, NSW 2041 (AU).

(74) Agents: **GLUCK, Peter, J.** et al.; Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *Without international search report and to be republished upon receipt of that report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PRE-SHAPED INTRALUMINAL GRAFT

(57) Abstract: An intraluminal graft having a predetermined substantially a linear configuration is ideally fitted within individuated aneurysmal regions, tortuous or primarily non-linear vessels, and a method of emplacing the same likewise discloses novel aspects.

WO 01/30270 A2

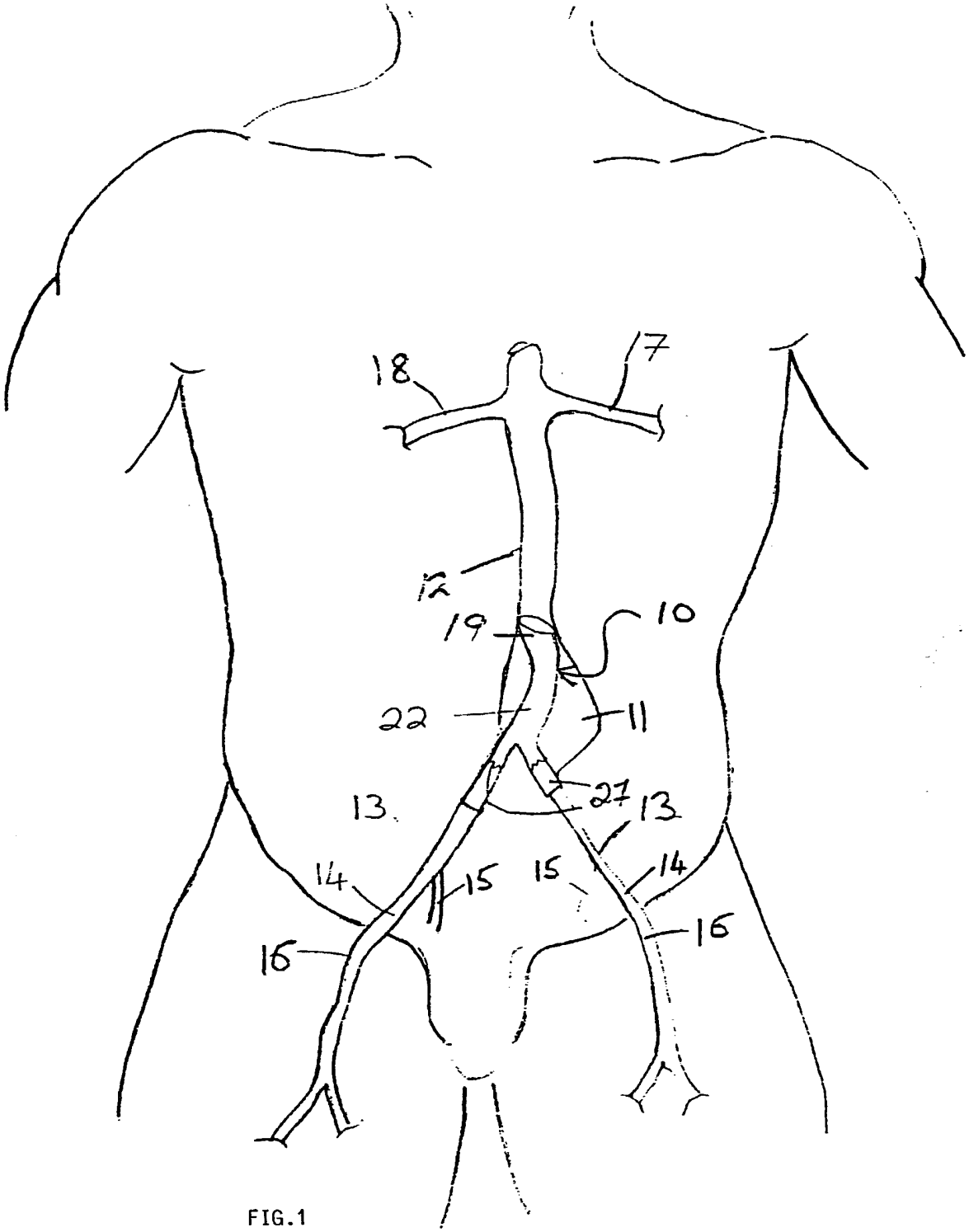


FIG.1

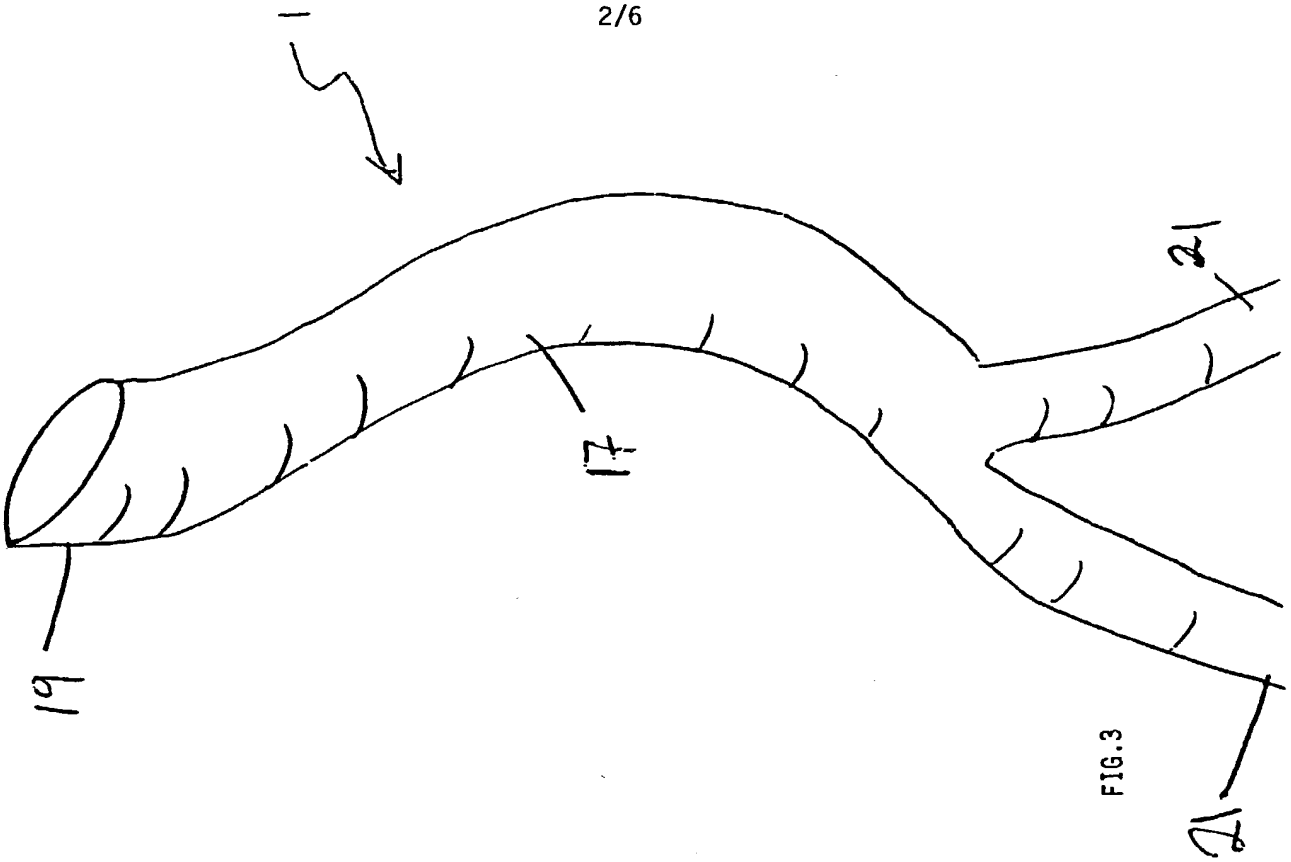


FIG.3

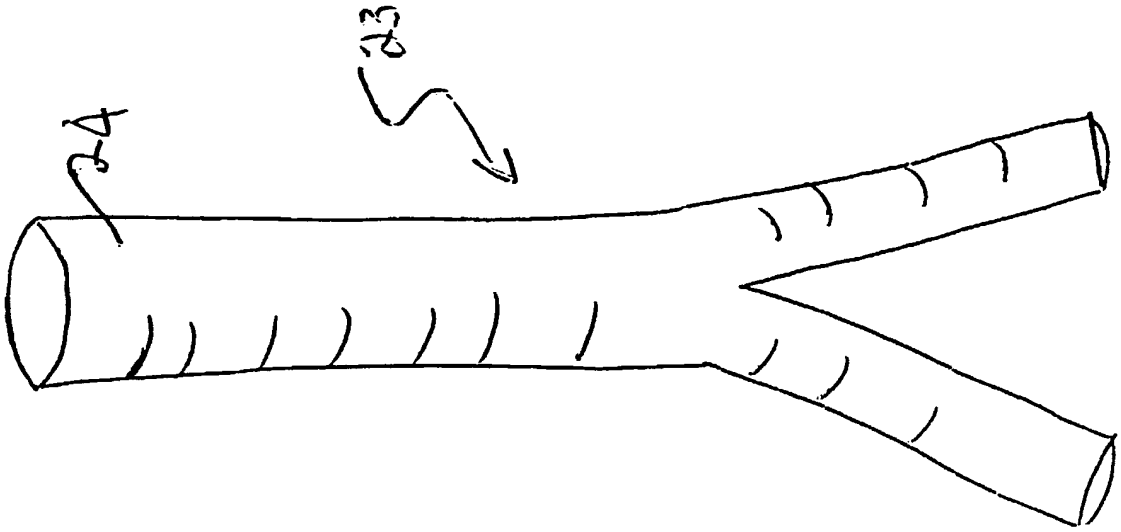


FIG.2

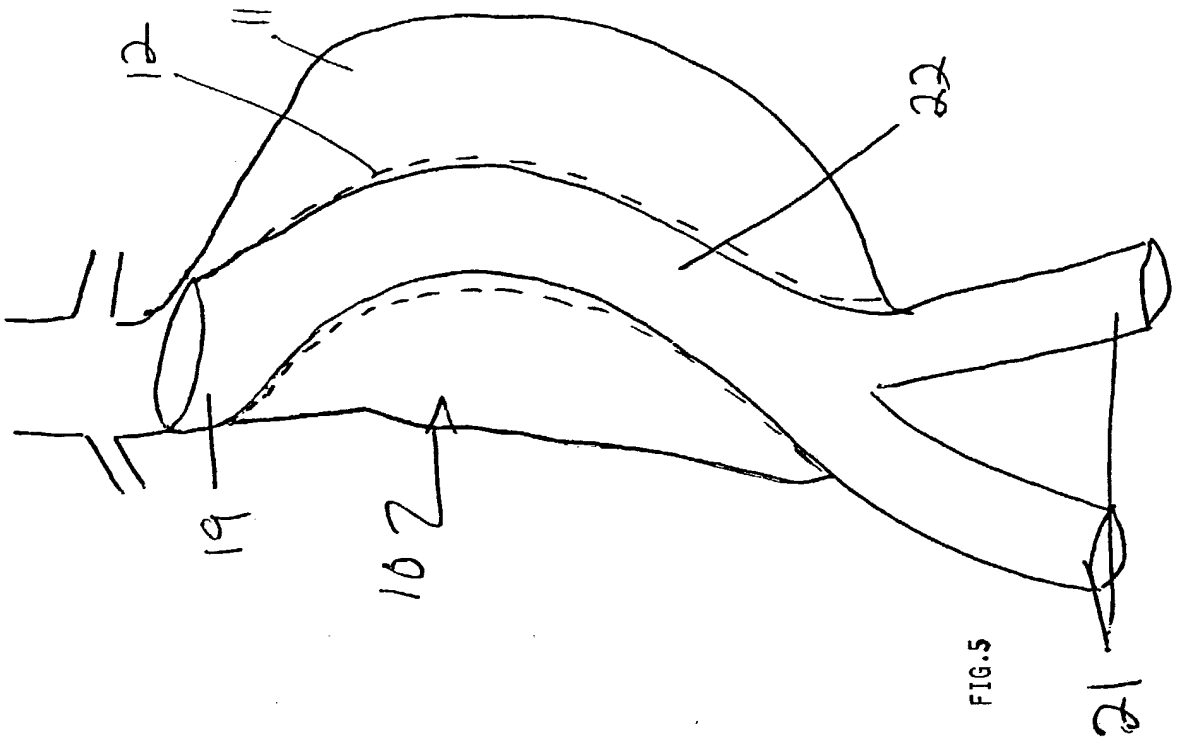


FIG.5

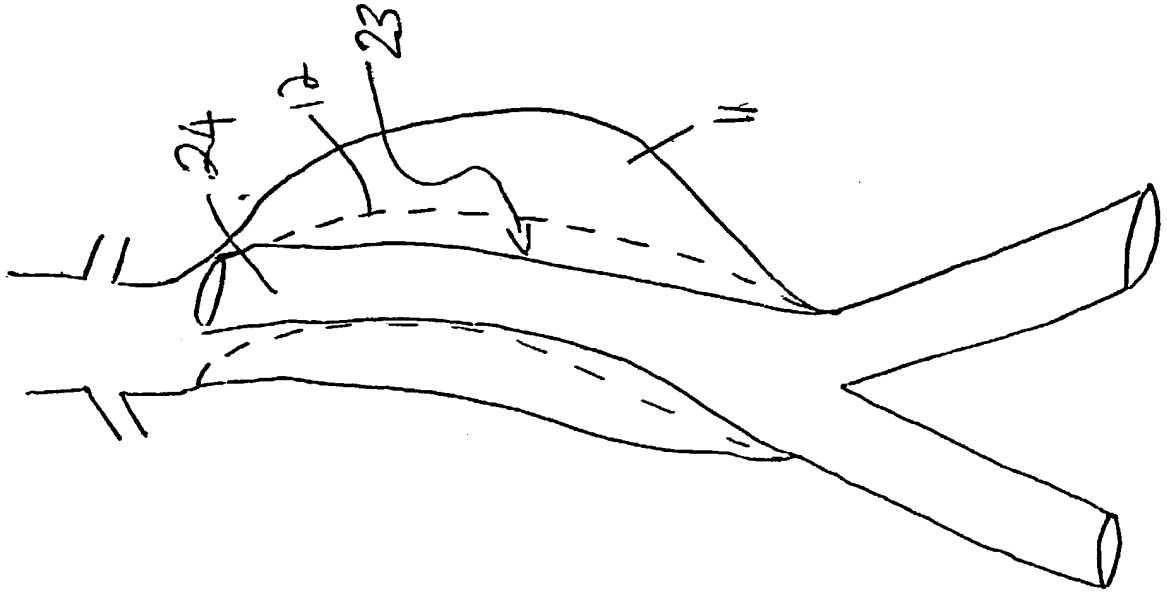


FIG.4

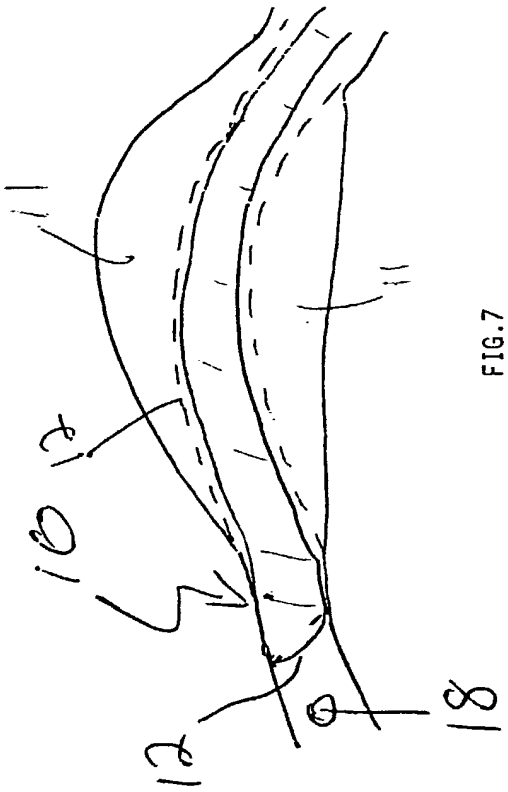


FIG.7

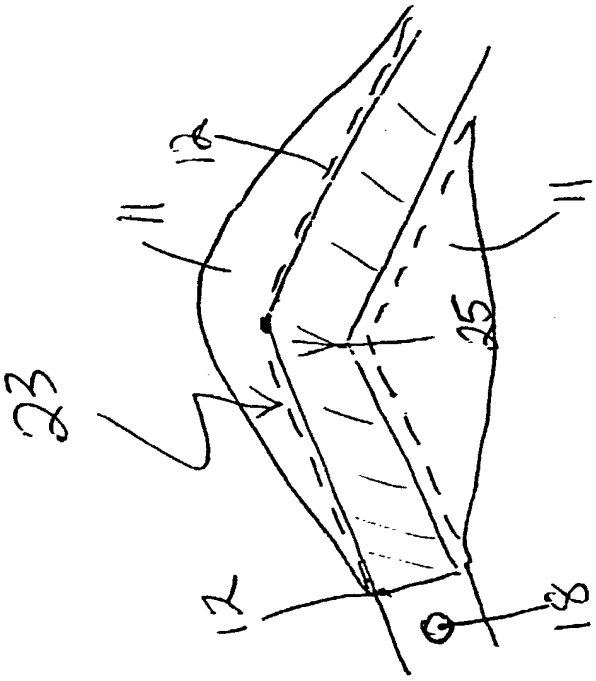


FIG.6

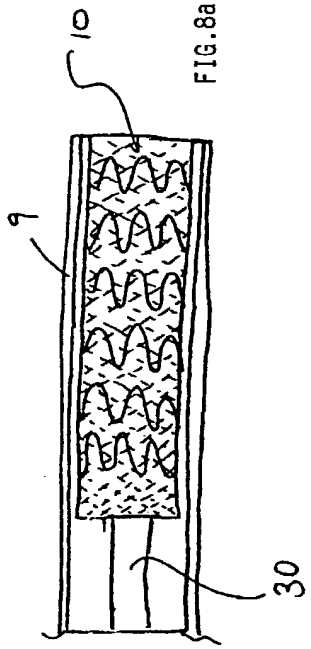


FIG.8a

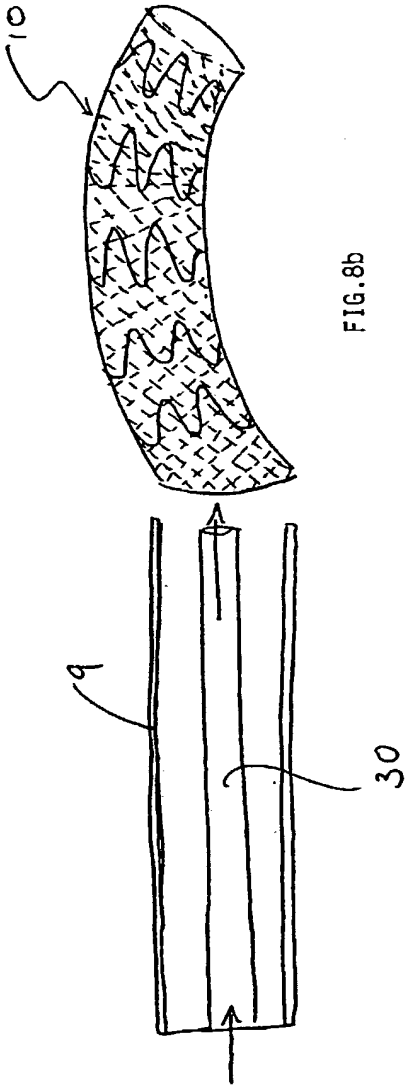


FIG.8b

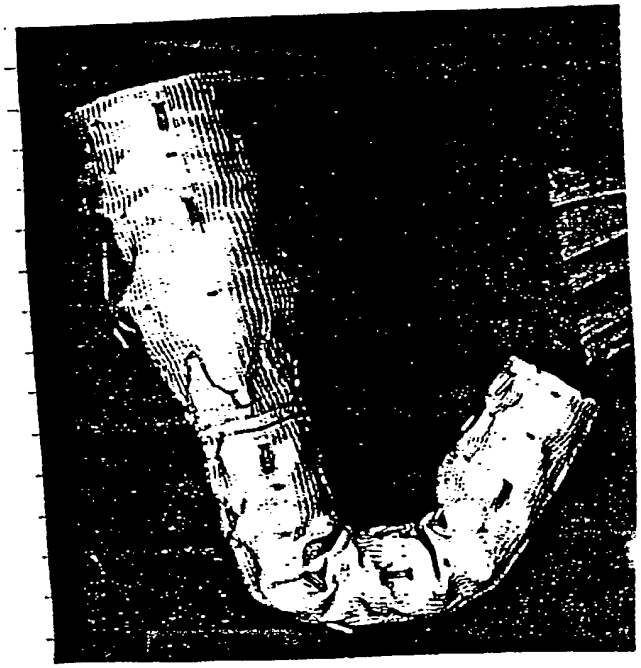


FIG.9

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My Residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and sole inventor (if only one name is listed below) or an original joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled PRE-SHAPED INTRALUMINAL GRAFT, the specification of which

(a) ___ is attached hereto
or
(b) XX as International Application No. PCT/US00/26239, International Application filing date of 09/25/00 and nationalized in U.S. as United States Application No. 10/088,937 filed on March 21, 2002.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information that is material to the examination of this application as defined in Title 37, Code of Federal Regulations, §1.56(a).

CIP Application Duty: If the present application is a continuation-in-part of any prior application(s), including any listed below or in the above-identified application, I acknowledge the duty to disclose information that is material to the examination of this application as defined in Title 37, Code of Federal Regulations, §1.56(a) which became available between the filing date of the prior application(s) and the national or PCT international filing date of this application.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign or provisional application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign or Provisional Application(s)			Priority Claimed	
Number	Country	Filing Date	Yes	No
PQ3029	Australia	09/23/99	X	

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below:

Application Serial No.	Filing Date
PCT/US00/26239	09/25/00

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office and in all the competent International Authorities connected therewith: Debra D. Condino, Reg. No. 31,007; Lena Vinitskaya, Reg. No. 39,448; Rajiv Yadav, Reg. No. 43,999; and John Christopher James, Reg. No. 40,660.

Address all correspondence and telephone calls to: Lena Vinitskaya
Edwards Lifesciences LLC
Law Dept.
One Edwards Way, Irvine, CA 92614
Telephone: (949) 250-6856, Facsimile: (949) 250-6850
Customer No. 30452

Docket No. VAS-5511A

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

1)

Full name sole or first joint inventor: Geoffrey H. White

Inventor's signature: X _____

Date: _____

Residence: 94 Louisa Road
Birchgrave, NSW 2041
Australia NSW AUX

Citizenship: Australia
Post Office Address: same

2)

Full name of second joint inventor: Mark Dehdashtian

Inventor's signature: X _____

Date: 9-25-02

Residence: 1996 Palaw Place
Costa Mesa, CA 92626 CA

Citizenship: US
Post Office Address: same

3)

Full name of third joint inventor: Teodoro S. Jimenez, Jr.

Inventor's signature: X _____

Date: 9/24/2002

Residence: 1025 La Marilla Circle
Corona, CA 92878 CA

Citizenship: US
Post Office Address: same

4)

Full name of fourth joint inventor: Weiyun Yu

Inventor's signature: X _____

Date: _____

Residence: Apt. 58 #8
Birchgrove, NSW 2041
Australia NSW AUX

Citizenship: Australia
Post Office Address: same

1166v1

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

Full name sole or first joint inventor: Geoffrey H. White

Inventor's signature: X G. H. White

Date: 9/26/02

Residence: 94 Louisa Road
Birchgrove, NSW 2041
Australia

Citizenship: Australia
Post Office Address: same

Full name of second joint inventor: Mark Dehdashtian

Inventor's signature: X_____

Date: _____

Residence: 1696 Palaw Place
Costa Mesa, CA 92626

Citizenship: US
Post Office Address: same

Full name of third joint inventor: Teodoro S. Jimenez, Jr.

Inventor's signature: X_____

Date: _____

Residence: 1025 La Marillo Circle
Corona, CA 92879

Citizenship: US
Post Office Address: same

Full name of fourth joint inventor: Weiyun Yu

Inventor's signature: X_____

Date: _____

Residence: Apt. 59 #8
Birchgrove, NSW 2041
Australia

Citizenship: Australia
Post Office Address: same

Docket No. VAS-5511A

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

Full name sole or
first joint inventor: Geoffrey H. White

Inventor's signature: X_____
Date: _____

Residence: 94 Louisa Road
Birchgrove, NSW 2041
Australia

Citizenship: Australia
Post Office Address: same

Full name of second
joint inventor: Mark Dehdashtian
Inventor's signature: X_____
Date: _____

Residence: 1696 Palaw Place
Costa Mesa, CA 92626

Citizenship: US
Post Office Address: same

Full name of third
joint inventor: Teodoro S. Jimenez, Jr.

Inventor's signature: X_____
Date: _____

Residence: 1025 La Marillo Circle
Corona, CA 92879

Citizenship: US
Post Office Address: same

Full name of fourth
joint inventor: Weiyun Yu

Inventor's signature: X_____
Date: 26 SEP 2002

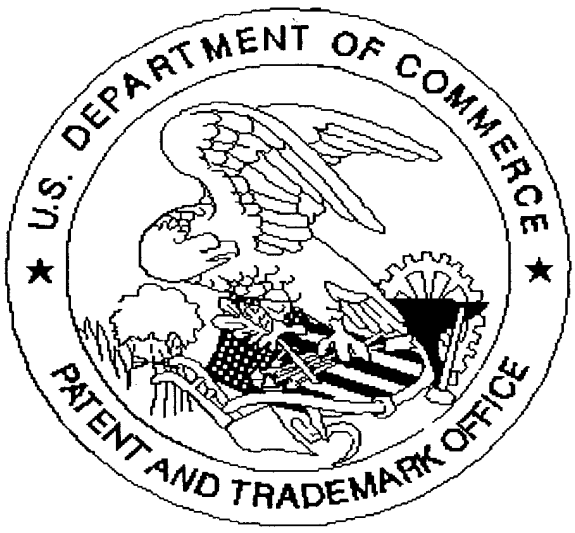
Residence: Apt. 59 #8
Birchgrove, NSW 2041
Australia

Citizenship: Australia
Post Office Address: same

1155v1

United States Patent & Trademark Office

Office of Initial Patent Examination -- Scanning Division



Application deficiencies found during scanning:

☐ Page(s)_____ of _____ were not present for scanning. (Document title)

☐ Page(s)_____ of _____ were not present for scanning. (Document title)

☑ ***Scanned copy is best available.*** Drawing Fig 3, is Dark